

PARAMETRICAL MODELING BASED MULTI-LAYERED APPROACH FOR DESIGN AND VALIDATION OF CATHETERIZATION DEVICES

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ABSTRACT

Minimally invasive surgery, a technique often performed without extended hospitalization, is increasingly getting popular. As next-generation medical procedures evolve, so does the need for next-generation medical devices and instrumentation. Medical device designers and manufacturers continue to introduce new products for surgeon's innovative uses.

Aiming to deploy and extend the simulation technologies of physical based modeling, visual and haptic interfacing, high fidelity imaging and advanced image processing for more effective medical device design and testing, we are currently developing CathWorks, an integrated design and validation system for catheterization devices. A parametrical modeling based multi-layered approach is developed in CathWorks for catheter device design. A backbone structure of three layers: geometry, function and information, is used to characterize the catheters through a feature-centered parametric methodology. A FEM engine is developed and embedded in CathWorks for validation of catheter design.

KEY WORDS: Catheterization, Simulation, Feature-based Design, Parametric Modeling, FEM

INTRODUCTION

Recent progresses in medical science and engineering have helped reducing the use of traditional "open" surgery, in which incisions are made to provide access to the operating area within the human body. Minimally invasive surgery, a technique often performed without extended hospitalization, is increasingly getting popular [1-2]. As "next-generation" medical procedures evolve, so does the need for next-generation medical devices and instrumentation. Medical device designers and

manufacturers continue to introduce new products for surgeon's innovative uses. However, with no realistic environment for validating the newly designed products, difficulty to explain the design features, and lacking communication between the designers and the surgeons are among the problems associated with current design systems for surgical and interventional devices, for example, the catheterization devices used in image-guided minimally invasive procedures. As a result, the development cycles and costs for new products are increased. In some cases, the designed devices could not meet the specific requirements from medical professionals.

The Medical Simulation Group at the Kent Ridge Digital Labs has been developing interventional simulators for performing realistic, real-time manipulation of vascular catheters in a virtual or augmented reality anatomical model of the human body and blood vessels [3-6]. Aiming to deploy and extend these simulation technologies of physical based modeling, visual and haptic interfacing, high fidelity imaging and advanced image processing for more effective medical device design and testing, we are currently developing CathWorks, an integrated design and validation system for catheterization devices.

CATHETERIZATION DEVICES

Catheters are main devices used in most catheterization procedures for passage through the arterotomy and into lumen of the selected artery (Figure 1). They are mostly slender structures with, in general, various circular and circular ring cross-sections. Their variations are specially designed to facilitate particular catheterization functions. Catheters are categorized according to their material, shape, length and functions.

They possess the properties of pliability, torqueability, and shape memory. Some catheters even serve multiple purposes in addition to their original intentions. A parametrical modeling based multi-layered approach is developed for catheter device design. A backbone structure of three layers: geometry, function and information, is used to characterize the catheters through a feature-centered parametric methodology.

Generally, a catheter is composed of several segments and the hook shape is its central part for performing access to a target artery. The shaft of the catheter is usually straight over most of its length. To achieve stiffness and torque control of the catheter shaft, stainless steel or nylon braiding in the middle layer of the body is used to back-up catheter insertion. The catheter tip is its most distal segment that may have single or multiple side holes in through, blind or spiral styles. The presence of side holes allows for increased contrast delivery with lesser tendency for catheter recoil. Some catheter tip designs may incorporate a soft tip. The hub of the catheter is bonded to the shaft and must have a strong, airtight seal. Catheter specifications may also be imprinted on the sleeve of the hub. Naturally, a feature-based modeling approach is most suitable for catheter building.

MULTI-LAYERED CATHETER MODELING

The geometry layer depicts the geometric features of the devices. The central curve of a catheter is defined parametrically by a sequence of rod points with a G^1 continuity constraint. The compound cross-section perpendicular to the central curve is governed by an explicit formula. It varies with multiple internal loops and single external close contour along the central curve. The profile description is expressed in terms of the central parameters and few other profile parameters that can vary independently. The surface geometry of a catheter is then piece-wisely constructed by sweeping the variable profile along the smooth central curve. Within this geometry layer, users can interactively design a catheter by, for example, using mouse controlled rubber-banding and rod modification. In the function layer, functional-based catheter features such as tip rounding, injection holing, tapering, are built on top of the geometry layer. An edge rounding technique with constant radius is used to construct the tip feature that may provide safety access to the blood walls. The flexibility of a catheter largely relies on the corewire design and the material used. CathWorks uses a sweeping operator to describe the corewire feature. This operation consists of combining circular motion and axial motion of a cross-sectional circle along a helical control curve. The helical control curve of the corewire is conjugate to the catheter central curve. Similarly, holing features can also be defined by cutting cylindrical objects off the main object at the specified points along the central curve and in given directions. In the information layer, a set of salient parameters of the catheter device is characterized to capture various attributes such as catheterization techniques, relevant interventional information, material properties,

sizes and shapes. With this multi-layered structure, CathWorks makes the catheter design and modification very efficient.

PARAMETRIC CATHETER DESIGN

The feature-based and parametrical modeling technique allows CathWorks to capture various similarities of the catheterization devices. Typical feature operations for catheter construction include shape sweeping, extruding, holing, braiding, shelling, and hub construction, etc. Doing so, users need to address only some predefined sets of values to create a device that is conformed to the respective norms. For the parametrically designed products, not only variational changes of the devices for designing and simulation become possible, but also the optimization of the parameters values considering given constraints can be performed. Figure 2 illustrates the catheter construction interface. Three design approaches are provided with CathWorks: (1) Shape library-based catheter design; (2) Model-based catheter design; and (3) Navigation-based catheter design.

A shape library that comprises of a list of curve shape for commonly used guiding and diagnostic catheters is built in CathWorks. Users can select one of the curve shapes from the library and then configure the catheter to be built by input the required length, french size of external diameter, internal diameter, hole style and parameters, wire braiding parameters and material properties of various segments.

Based on the variational vascular modeling, CathWorks allows users to select vessel segments and define a cross-sectional plane to section the vascular model. A drawing sketch can then be created from the cross-sectional plane and users can freely draw a curved hook shape on the sketch with reference to the vascular model. Users can interactively modify the curve shape at this stage to obtain satisfactory result. This method creates planar curve shape based on the vasculature model. When a "new design" of the curve shape is generated, CathWorks is ready to construct the catheter with given catheter configuration. By selecting the "new design" for curve shape, users can activate the same user interface (Figure 2) to set various parameters and start building catheter.

Users can insert a virtual guidewire/catheter at femoral or brachial position of a virtual human vasculature and then navigate it inside the blood vessels by a sequence of pushing, pulling and twisting operations until it reaches the region of target arteries. The head portion of the catheter is then recorded as a new design curve shape for catheter construction. Figure 3 shows the virtual catheter/guidewire inserted in the human vasculature to form a proper hook shape for catheter construction.

CATHETER DESIGN VALIDATION

A real-time finite element analysis engine is embedded in CathWorks to provide the functional testing and validation of the newly designed catheters. The finite element meshes of the catheters can be easily generated from the central curve and profile formula of the geometry layer while the material properties of the various parts of the catheter can be obtained from the information layer. The flexibility of the catheter tip, and the force-displacement of the catheter can be immediately tested within the integrated design-validation environment. The material of the catheter tip can be modified during the test process (Figure 4). Furthermore, the catheters can also be verified via a real-time navigating procedure in a simulated vasculature of human anatomy. The segmented vascular anatomy of blood vessels are reconstructed from MRI or X-ray angiographic images to make the testing environment more realistic and similar to actual clinical catheterization procedures. The rebuilt vasculature from real patient images can also be used, eventually, as references for customized design and testing of catheterization devices. With the parametric based multi-layered structure, real time FEM modeling and realistic human vasculature environment, CathWorks provides an integrated solution to design and validate the catheterization devices.]

CONCLUSIONS

Catheter manufacturing is a very lucrative business emerging from high-technology development in the minimal invasive surgery. A parametric and feature-based approach is developed with the CathWorks system to design and validate the catheter devices. CathWorks is built upon the SolidWorks® modeling toolkit within the Intel PC and Window NT platform. With Visual C++ programming, a group of dynamic link libraries have been implemented based on the SolidWorks® API. A FEM engine is embedded in the CathWorks that provides efficient validation and design analysis. The human vasculature is modeled within the OpenGL® environment and plugged in the SolidWorks® design toolkit.

ACKNOWLEDGMENT

The authors would like to thank National Science and Technology Board of Singapore for funding this research.

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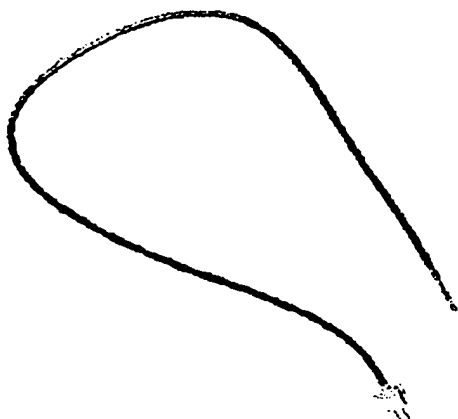


Figure 1. A catheter designed by CathWorks is characterized by its length, external and internal diameters, injection holes, curve shape and materials, etc.

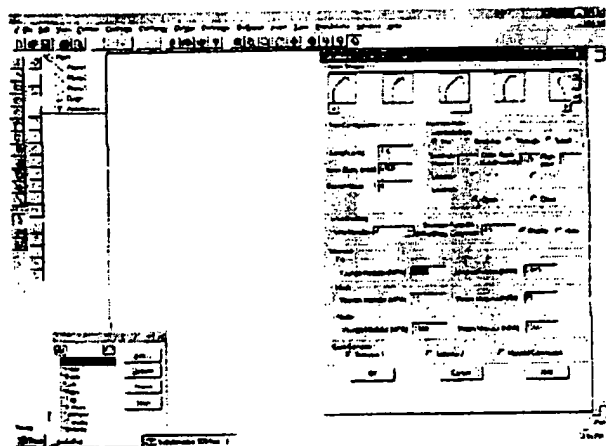


Figure 2. The user interface for catheter construction.

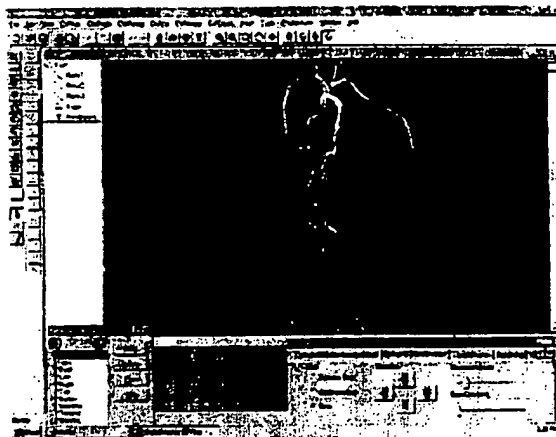


Figure 3. Human vasculature navigation based catheter design.

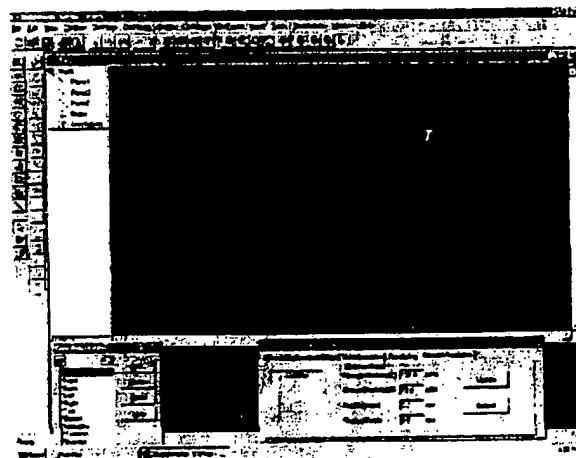


Figure 4. Validate the design by force-displacement test with various material properties

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VOLUME 15, Number 1, 2000

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Preface

It is my great pleasure to introduce this special issue of the International Journal of Robotics and Automation. This special issue contains papers selected from over 50 high-quality papers presented at the IASTED International Conference on Computer Graphics and Imaging 99 (CGIM'99). The conference was held in Palm Springs, California, USA, from October 25 to 27, 1999. It was a major contact point for scientists, engineers, and researchers throughout the world in the wide arena of disciplines under computer graphics and imaging, to present and share their latest research, developments, and ideas. The conference papers featured major topics of computer graphics and imaging.

This special issue contains six papers:

- "Automatic Mesh Refinement and its Application to Radiosity Computations", by R. Danforth and R. Geist
- "Virtual Postman — An Illustrative Example of *Virtual Video*", by A. J. Lipton
- "Motion Correction of Myocardial Perfusion Spect employing Image Enhanced Diverging Square Algorithm", by M.H.N. Tabrizi, K. Dong, R. Owens, R. Scardigno, S. Eubanks, and A. Movahed
- "Motion Detection from a Moving Observer using Pure Feature Matching", by Z. Hu and K. Uchimura
- "Catheter Design, Validation and Presentation using CathWorks", by Y.Y. Cai, Y.P. Wang, X. Ye, C.K. Chui, Y.T. Ooi, and K.H. Mak
- "Three-dimensional Wavelet Coding of Volumetric Imagery", by J. Vass, K. Palaniappan, and X. Zhuang

These papers cover aspects of feature matching, imaging, medical application, modelling, motion detection, motion correction, simulation, texture, visualization and virtual environments. They are selected based on the session chairs' recommendations and are further reviewed and selected based on the reviewers' evaluations.

From this editorial preface, I would like to thank the authors for their excellent work. I would like also to thank the International Program Committee members and the session chairs for their swift and sound analyses, recommendations, and decisions. My special thanks go to Dr. M.H. Hamza and other IASTED conference organizers who made CGIM'99 successful and this special issue possible.

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